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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,052	06/25/2001	Bettina Moeckel	204212US0X	7077

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/17/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

09/887,052

Applicant(s)

MOECKEL ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/27/2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-36,38 and 40-94 is/are pending in the application.
- 4a) Of the above claim(s) 11-17,20-23,26-29,32-35,42-82 and 85-87 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,3,4,18,19,24,25,30,31,36,38,83 and 84 is/are allowed.
- 6) ☒ Claim(s) 2,6-10,40,41 and 88-94 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicants cancellation of claims 5, 37 and 39, amendment of claims 2, 6, 7, 8, 10, 40-43 and the addition of new claims 88-94, Paper No. 11, 3/27/2003, is acknowledged. Claims 1-4, 6-36, 38, and 40-87 are at issue and are present for examination.

Applicants' arguments filed on 3/27/2003, paper No. 11, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 11-17, 20-23, 26-29, 32-35, 42-82 and 85-87 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 7.

Information Disclosure Statement

Applicants filing of information disclosures, Paper No. 8, filed 12/6/2002, is acknowledged, however as previously stated many of the references are missing and have therefore not been considered. Applicants have not responded to the missing references noted in the previous office action.

Applicants filing of information disclosures, Paper No. 10, filed 3/27/2003, is acknowledged.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 9, 40, 41, 92, 93 and 94 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 9, 92 (claim 93 dependent on) and 94 are indefinite in that they recite "...activity of the β -subunit of RNA polymerase B." As stated in the previous office action, it is unclear what "activity of the β -subunit of RNA polymerase" applicants refer. A biologically active protein may encompass a variety of different biological activities. These include but are not limited to immunological activity, such as acting as an antigen for an antibody; regulatory activity, such as that exhibited by many proteins which control transcription and/or translation of not only their encoding nucleic acids but other nucleic acids as well; or enzymatic activity, for example, RNA polymerase activity. It is not clear what is encompassed by the "activity" of β -subunit of RNA polymerase B and if includes biological activities in addition to enzymatic activity. Newly added claim 92 (93 dependent on) and 94 are included in this rejected for the same reasons discussed for claims 2 and 9 above.

Applicants traverse this rejection by presenting the reference, Stryer et al. Biochemistry, (1988) and stating that "the activity of the β -subunit of RNA polymerase B" is to bind a DNA template, bind ribonucleotide triphosphate substrates and form

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phosphodiester bonds" and that thus clearly one skilled in the art at the time of invention would understand the clear definition of "a protein having activity of the β -subunit of RNA polymerase B". Applicants argument is not found persuasive on the basis that while many of the activities of the β -subunit of RNA polymerase B are understood, it is understood that the β -subunit of RNA polymerase B has many activities and it remains unclear as to which of these activities if not all applicants refer. This is further pointed out in applicants claims 2-9 in which applicants refer to "an activity of the β -subunit " and "the activity of the β -subunit", respectively. Clearly applicants have pointed out that the b-subunit of RNA polymerase B has at least 3 different activities.

Claim 40 (41 dependent on) remains indefinite in that it is unclear in that it is drawn to "A *Coryneform* bacterium which comprises an enhanced rpoB gene." Applicants argued that "the expression of the protein which is encoded by the polynucleotide is enhanced, however, applicants amendment of the claim is such that "the protein encoded by the polynucleotide is enhanced". This still remains unclear in that it is unclear how the protein is enhanced, applicants state that the expression of the protein is enhanced, however applicants amendment reads on any enhancement of the protein, i.e. expression or activity etc...

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 6-10 and 88-94 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action as it applied to claims 5-10. In response to this rejection applicants have cancelled claim 5 and amended claims 6-8 and 10. Applicants traverse this rejection as well as the rejection below based on 112 first paragraph and a lack of enablement together. Applicants traverse that based on applicants amendment "to specify that the claimed polynucleotide encodes a polypeptide having activity of the β -subunit of RNA polymerase B", withdrawal of the rejection is respectfully requested. As discussed above while applicants have argued that the claimed β -subunit of RNA polymerase B has specific activities, applicants amendment of the claims is not successful in overcoming the rejection and thus the previous rejection remains based on it is unclear as to what "activity" of the β -subunit of RNA polymerase B applicants are referring to. Hence, there is no disclosure of any particular structure to function/activity relationship in the disclosed species. The specification fails to describe additional representative species of the claimed polynucleotides by any identifying structural characteristics or properties. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the

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claimed invention. Claims 88-94 are included in this rejection for the same reasons as applied to claims 6-10 above and in the previous office action.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 10 and 88 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 10 (claim 88 dependent on) is rejected under this statute because the newly added recitation "...at least 35 consecutive nucleotides of nucleotides 702 to 4199 of SEQ ID NO: 1, and at least 25 consecutive nucleotides of nucleotides 4200 to 5099 of SEQ ID NO:1" is not supported by the original specification and therefore considered new matter.

Claims 6-10 and 88-94 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polynucleotide which encodes a protein having the amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement for any polynucleotide which comprises a mere 15 consecutive nucleotides of SEQ ID NO: 3 or is 70-90% identical to SEQ ID NO: 1. The specification does not

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enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was stated in the previous office action as it applied to claims 5-10. In response to this rejection applicants have cancelled claim 5 and amended claims 6-8 and 10. Applicants traverse this rejection as well as the rejection below based a lack of enablement together with the above 112 first paragraph rejection and written description.

Applicants traverse that based on applicants amendment "to specify that the claimed polynucleotide encodes a polypeptide having activity of the β -subunit of RNA polymerase B", withdrawal of the rejection is respectfully requested. As discussed above while applicants have argued that the claimed β -subunit of RNA polymerase B has specific activities, applicants amendment of the claims is not successful in overcoming the rejection and thus the previous rejection remains based on it is unclear as to what "activity" of the β -subunit of RNA polymerase B applicants are referring to.

Hence, the scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides broadly encompassed by the claims. The claims rejected under this section of U.S.C. 112, first paragraph, place insufficient functional limitations on the claimed polynucleotides. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are

tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. The same is true of a polynucleotide sequence, as the nucleic acid sequence of the polynucleotide directly correlates with the amino acid sequence of the polypeptide. However, in this case the disclosure is limited to a polynucleotide which encodes a protein having the amino acid sequence of SEQ ID NO: 2. Claims 88-94 are included in this rejection for the same reasons as applied to claims 6-10 above and in the previous office action.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any polynucleotide with the claimed structural relationship to SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a long horizontal stroke extending to the right.

Richard G Hutson, Ph.D.
Primary Examiner
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June 9, 2003